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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,228	02/09/2005	Alan John Johnstone	205139 (8830-308)	1559
7590 Gregory J Lavorgna Drinker Biddle & Reath One Logan Square 18th & Cherry Street Philadelphia, PA 19103-7595				
01/11/2010				
EXAMINER				
NATNITHITHADHA, NAVIN				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
01/11/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/524,228

**Applicant(s)**

JOHNSTONE, ALAN JOHN

**Examiner**

NAVIN NATNITHADHA

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB006)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. According to the Amendment, filed 06 October 2009, the status of the claims is as follows:

Claim 1 is currently amended;

Claim 2 is as originally filed;

Claims 3, 5-9, and 11 are previously presented; and

Claims 4, 10, and 12-23 are cancelled.

### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Previously cancelled claims 13-23 do not appear in the claims in the Amendment filed 06 October 2009.

### ***Response to Arguments***

3. Applicant's arguments, see Remarks, pp. 4-5, filed 06 October 2009, with respect to the rejection of claims 1-3, 5-9, and 11 under 35 U.S.C. 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

4. Applicant's arguments, see Remarks, pp. 5-10, filed 06 October 2009, with respect to the rejection of claims 1-3, 5-9, and 11 under 35 U.S.C. 102(b) as being directed to non-statutory subject matter, have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, p. 5, the following:

Applicant respectfully submits that Applicant's present claims are method or process claims that do actually transform underlying subject matter, and are entirely different to Bilski's claims.

However, this argument is not persuasive. The claims do not pass the "machine-or-transformation test" because, although a machine, i.e. a "pH sensor", is recited, the use of the particular machine does not impose a meaningful limit on the claim's scope. The use of the particular machine does not involve more than insignificant extra-solution activity. Instead, the use of the particular machine, i.e. the "pH sensor", is used for mere data gathering, i.e. "measuring intracompartmental pH".

5. Applicant's arguments, see Remarks, pp. 11-16, filed 06 October 2009, with respect to the rejection of claims 1-3, 5-9, and 11 under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Greene et al, U.S. Patent No. 6,238,339 B1 ("Fiddian-Greene"), in view of Sacristan et al, U.S. Patent No. 5,158,083 A ("Sacristan"), have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these claims are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. *See Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). *See also In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Circ. 2008), where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101.

The claims do not pass the "machine-or-transformation test" because, although a machine is recited, the use of the particular machine, i.e. a "pH sensor", does not impose a meaningful limit on the claim's scope. The use of the particular machine does not involve more than insignificant extra-solution activity. Instead, the use of the particular machine, i.e. the "pH sensor", is used for mere data gathering, i.e. "measuring intracompartamental pH".

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7. Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101 since the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. The language 'including within its scope a human being' is the important language here. The claim positively recites a part of the human body, it is directed to nonstatutory subject matter.

*Commissioner Quigg's notice*, entitled "Animals – Patentability", 1077 OG 24 (April 21, 1987); and see also *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under **35 U.S.C. 101** must be made indicating that the claimed invention is directed to nonstatutory subject matter." MPEP 2105. Because claim 1 recites the limitation "a person using the intracompartmental pH measurement to determine the presence or severity of ischemia and to diagnose the pathological condition" (emphasis added by Examiner), the claim positively recites naturally occurring matter.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

9. Applicant's amendment, filed on 06 October 2009, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **NAVIN NATNITHITHADHA** whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
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/N. N./  
Patent Examiner, Art Unit 3735  
01/14/2010